# Neonatal Respiratory Distress in a Poor Resource Setting: From Epidemiology to Outcome


## Abstract

**Background**: Neonatal respiratory distress one of the main causes of neonatal morbidity and mortality. It is a diagnostic and therapeutic emergency whose etiology is dominated by respiratory pathologies. **Objective**: To study the epidemiological, clinical, diagnostic, therapeutic, and outcomes aspects of neonatal respiratory distress in order to help reduce its impact on neonatal morbidity and mortality. **Methods**: A retrospective descriptive cross-sectional studycovering the period from 1st January 2017 to 31 December 2018 was conducted in the Neonatology Unit of the Centre HospitalierUniversitairePédiatrique Charles de Gaulle of Ouagadougou, Burkina Faso (West Africa). The clinical records of newborns admitted for respiratory distress (n=305) were included in the study. **Results:** Over the two-year period, the frequency of neonatal respiratory distress was 39.1% (305/780). Factors of respiratory distress were early neonatal period (80%), male sex(60.7%), full-term birth (82.3%), and normal birth weight (66.3%). The Silverman and Andersen score was mild (20.4%), moderate (68.5%), and severe (11.1%). The main causes of respiratory distress were neonatal septicemic infection (59.3%) and perinatal asphyxia (30.5%). Treatment mainly includes cardiopulmonary resuscitation, maintenance of fluid and electrolyte balance, and oxygen therapy. There were 83 deaths, giving a case-fatality rate of 27.2%. Major causes of death were sepsis (13.1%) and perinatal asphyxia (9.8%). **Conclusion**: Neonatal respiratory distress is common in our neonatal unit. In order to reduce neonatal morbidity and mortality linked to this condition, action must be taken to combat neonatal sepsis, perinatal asphyxia, and preterm birth.

**Keywords**: Newborn, Hyaline membrane disease, Transient tachypnea of the newborn, Meconium aspiration syndrome, Congenital malformations.

## Introduction

Neonatal respiratory distress (NRD) refers to the set of clinical signs observed among newborns with disturbed pulmonary gas exchange [1]. This is an issue of quadruple interest. First, epidemiologically, this morbidity constitutes an important reason for hospitalization in neonatology units, with a frequency ranging from 42.9% [2] to 71.35% [3]. Secondly, diagnostically, NRD is an emergency that needs to be diagnosed fast. The diagnosis is straightforward and clinical and is made on the basis of observation of the triad of inspection signs, alone or more often in combination (Table 1).

***Table 1: Positive diagnosis of neonatal respiratory distress***

| **Clinical examination (Inspection)** | **Sign** |
|---|---|
| 1. Changes in breathing rate | - tachypnea >60 c/min.<br>- bradypnea <40 c/min. |
| 2. Signs of respiratory struggle | - expiratory grunting<br>- intercostal retraction<br>- supra-sternal retraction<br>- xiphoid retraction<br>- nasal flaring<br>- thoracic-abdominal rocking |
| 3. Cyanosis | Blue discoloration of lips, inner cheeks, palms, soles of feet |

Once a positive diagnosis has been made, the severity of the disease must be urgently assessed using signs of respiratory struggle quantified by the retraction index or Silverman and Andersen score [4]. From a diagnostic point of view, identifying the cause is a top

priority which can be achieved through the triple approach of medical history, physical examination, and para-clinical investigations. There are many causes that are dominated by respiratory diseases [5,6]. Thirdly, a therapeutic interest is represented by the urgent need for treatment without delay, at the risk of complications. Finally, fourthly, the prognostic interest lies in the jeopardy to the newborn's life in case of delayed diagnosis and/or treatment. Deaths are frequent, often exceeding 20% of cases [3,7,8].

NRD, therefore, represents a major challenge in pediatric care. Hence, understanding the underlying causes of this condition, as well as, the appropriate assessment methods and interventions, is utmost crucial to healthcare professionals for the survival of newborns.

The aim of this study was, therefore, to examine the epidemiological, clinical, diagnostic, therapeutic, and outcomes aspects of NRD, focusing on the pre-and postnatal factors that may influence its onset. By analyzing the available data, the authors hope to provide healthcare professionals with a knowledge base for understanding and managing NRD.

## Materials and methods

### *Study context*

A cross-sectional study was conducted in the Neonatology Unit (NU) of the Centre HospitalierUniversitairePédiatrique Charles de Gaulle (CHUP-CDG) in Ouagadougou, the capital of Burkina Faso (West Africa), a low-income country. The equipment includes neonatal resuscitation tables, radiant and closed incubators, oxygen, manual ventilation equipment (self-inflating balloons, masks, goggles), conventional and intensive phototherapy equipment, monitoring scopes, and electric mucus aspirators. Medicines (caffeine, anticonvulsants, antibiotics, etc.) are available from a hospital pharmacy that dispenses them individually by name. The continuous positive airway pressure (CPAP) and infant flow

devices are not operational. As the CHUP-CDG does not have a maternity ward, the admission of newborns is direct by transfer from the city's maternity wards.

*Type and period of study*

A retrospective descriptive cross-sectional study was conducted over the period from January 1st, 2017to December 31, 2018.

*Sampling*

The study population consisted of all newborns hospitalized in the NU during the study period. The clinical records of newborns admitted for respiratory distress (RD) (n=305) during the study period were included in this study, whereas, clinical files of malformed children were not included. The newborns meeting the inclusion criteria constituted the sample.

*Studied variables*

The variables were categorized as epidemiological (frequency, sex), clinical (age at admission, term of birth, route of birth, birth weight, Apgar score), diagnostic (investigations, etiologies), therapeutic (treatments), and outcomes( duration of hospitalization, complications, mode of discharge).

*Data collection and analyze*

The data were collected using the admission registers, monthly reports, hospital statistics, and patients' clinical records. A standardized, anonymized form designed for the purpose of this study was used to collect the information. The information was then entered on a microcomputer using Epi Info® (CDC, Atlanta) and analyzed using the same software. For qualitative variables, frequency distributions were generated and for quantitative variables, the mean and standard deviation were calculated.

**Results**

*Epidemiological findings*

Over the two-year period covered by the study, a total of 780 newborns were hospitalized in the NU, of which, 39.1% (305/780) were admitted for RD. The sex ratio was 1.5 (185/120).

*Clinical features*

In 25.2% of cases (77/305), the newborns were admitted on the day of birth (Day 0), whereas, the majority of the sample ie, 80.0% (244/305) were admitted in the early neonatal period (Day 0-Day 6). Also, there were 20.0% (61/305) newborns aged between 7 and 28 days (late neonatal period).

The birth was through normal vaginal delivery in 64.2% (192/299) of cases, dystocic vaginal delivery in 21.1% (63/299), and Caesarean section in 14.7% (44/299) of cases. Full-term newborns accounted for 82.3% (247/300), whereas, premature newborns accounted for 17.7% (53/300) of cases. The birth weight was normal for 66.3% (199/300) of newborns, whereas, low birth weight (LBW) and macrosomic newborns accounted for 31.7% (95/300) and 2% (6/300) of cases, respectively. The Apgar score at the $5^{th}$ minute was less than 7 in 15.9% (44/276) of cases, and equal to or greater than 7 in 84.1% (232/276) of cases.

Newborns were apyretic in 49.2% (150/305) of cases; 32.1% (98/305) had a fever, and 18.7% (57/305) were hypothermic. Mean peripheral pulsed oxygen saturation ($SpO_2$) was 80%±19.22 [52-100], with hypoxia ($SpO_2$ <95%) accounting for 56.8% (170/299) of cases. The mean respiratory rate was 45±12 c/min. [35, 60]. Signs of NRD are detailed in Table 2.

***Table 2: Frequency of signs of neonatal respiratory distress, Ouagadougou, 2018, Burkina Faso (n = 305)***

| Sign of respiratory distress | Frequency | % |
|---|---|---|
| Nasal flaring | 281 | 92,1 |
| Cyanosis | 226 | 74,1 |
| Intercostal retraction | 215 | 70,5 |
| Grunting | 200 | 65,6 |
| Xiphoid retraction | 185 | 60,7 |
| Supra-sternal retraction | 175 | 57,4 |
| Polypnea | 138 | 45,2 |
| Thoracic-abdominal rocking | 101 | 33,1 |
| Bradypnea | 75 | 25,4 |

The mean Silverman and Andersen score was 5±3 [3, 8]. RD was mild in 20.4% (62/305), moderate in 68.5% (209/305), and severe in 11.1% (34/305) of cases.

*Diagnostic tests and results*

Chest X-rays were requested for 55.1% (168/305) of newborns, among which abnormalities were found in 9.5% (16/168) of cases. Similarly, cardiac ultrasound was requested for 21.3% (65/305) of newborns, of which 7.7% (5/65) showed congenital heart disease.

Table 3 shows the causes of NRD, which were dominated by neonatal infection in its septicemic form, perinatal asphyxia, and respiratory infections.

***Table 3: Etiology of neonatal respiratory distress, Ouagadougou, 2018, Burkina Faso (n=305)***

| Etiology of neonatal respiratory distress | Number of cases | % |
|---|---|---|
| **Septicemia** | 181 | 59.3 |
| **Perinatal asphyxia** | 93 | 30.5 |
| **Respiratory infection** | 21 | 6.9 |
| Bronchopneumonia | 82 | 2.6 |
| Pneumonia | 1 | 0,3 |
| Pleural-pulmonary staphylococcic | 1 | 0.3 |
| **Others respiratory diseases** | 19 | 6,2 |
| Transient tachypnea of the newborn | 11 | 3.6 |
| Membraneshyaline disease | 5 | 1.6 |
| Meconium aspiration syndrome | 2 | 0.6 |
| Obstructive rhinitis | 1 | 0.3 |
| **Malformations** | **10** | **3.3** |
| Congenital heart disease | 7 | 2.3 |
| Poly malformation syndrome | 1 | 0.3 |
| Laryngomalacia | 1 | 0,3 |
| Choanal atresia | 1 | 0,3 |
| **Other causes** | **10** | **3.3** |
| Poisoning from traditional products | 8 | 2.7 |
| Hemorrhagic disease of the newborn | 2 | 0.6 |

*Therapeutic resources*

Treatment consisted of infusions of solutes with electrolytes in all cases. Table 4 shows the different treatments such as infusions, antibiotics and oxygen received by newborns presenting with RD.

***Table 4: Treatment of neonatal respiratory distress, Ouagadougou 2018, Burkina Faso (n=305)***

| **Treatment** | **Number of cases** | **%** |
|---|---|---|
| Solute infusion (glucose, saline, bicarbonate serum) plus electrolytes | 305 | 100.0 |
| Antibiotic (cefotaxime, gentamicin) | 300 | 98.4 |
| Oxygen therapy | 210 | 68.9 |
| Upper airways decongestion | 37 | 12.1 |
| Warming | 36 | 11.8 |
| Caffeine | 21 | 6.9 |

*Outcomes*

Acute complications noted were represented by RD exacerbation (23.7%), airway flooding (17.6%), apneas (9.9%), and respiratory exhaustion (6.2%). Newborns were discharged in 71.5% (218/305) of cases, whereas, deaths numbered 27.2% (83/305) newborns and 1.3% (4/305) newborns were discharged against medical advice. The cause of death is shown in Table 5.

***Table 5: Cause of death of newborns presenting with neonatal respiratory distress, Ouagadougou 2018, Burkina Faso (n=305)***

| Main cause of death | Number of cases of deaths | Mortality rate (%) |
|---|---|---|
| Sepsis | 40 | 13.1 |
| Perinatal asphyxia | 30 | 9.8 |
| Respiratory infection | 3 | 1.0 |
| Congenital heart disease | 3 | 1.0 |
| Hyaline membrane disease | 2 | 0.7 |
| Poly malformation syndrome | 1 | 0.3 |
| Meconium aspiration syndrome | 1 | 0.3 |
| Laryngomalacia | 1 | 0.3 |
| Poisoning from traditional products | 1 | 0.3 |

**Discussion**

The present study showed that the frequency of NRD was 39.1%, significantly higher than that observed in another hospital in Ouagadougou (20.6%) [9]. In sub-Saharan Africa, a frequency of 47.5% was observed in Cameroon [10] and 58.4% in Nigeria [11]. In the Middle East, a frequency of 36.1% is reported in Syria [5], while it reaches to 84.8% in Iraq [8]. In Asia, this frequency varies from 4.4% in India [6] to 34.3% in Nepal [12].

The variability in the frequency of NRD observed in different regions can be attributed to several factors, such as: a) Levels of maternal and neonatal healthcare: Countries or regions with better access to maternal and neonatal healthcare, including prevention, screening, and

treatment services, are likely to have a lower frequency of NRD. On the other hand, regions with limited or unequal access to adequate medical care may have a higher frequency; b) Medical care practices: Differences in medical and neonatal practices, including preterm birth management, respiratory support, and infection prevention, may contribute to variability in NRD frequency; c) Nutritional status of mother and newborn: Maternal nutrition during pregnancy and breastfeeding, as well as, newborn nutrition, can influence lung development and respiratory capacity, which may affect the risk of NRD; d) Access to medical technology: Technological advances in medical care and the availability of specialized equipment may vary from one region to another, which may have an impact on the detection and management of NRD; e) Prevalence of risk factors: The frequency of certain risk factors, such as prematurity, maternal infections, high blood pressure, maternal smoking, and multiple births, may vary from one region to another, which will have an impact on the overall incidence of NRD. It is important to note that the combination of several of these factors may contribute to the variability in the incidence of NRD in different regions. Further research and epidemiological studies are needed to better understand these variations and develop appropriate strategies to reduce the incidence of this serious condition in newborns.

This study showed that one in four newborns with RD were admitted to the hospital within 24 hours of delivery. Also, most hospitalizations occurred during the first week of life and only one in five babies were admitted after one week. Similarly, 90.4% of NRD cases were admitted to the hospital during the first week of life in the city of Ouagadougou [9]. Some authors reported a higher percentage of admissions within the first 24 hours, ranging from 70.8% [11], 77.2% [7], to 83.8% [10], with a gradual decrease in admissions over the following days. The period around birth, especially the initial hours and days of life, poses a challenge for newborns in adapting to life outside the womb, particularly concerning their

cardio-respiratory function. This explains the higher incidence of respiratory distress observed during the early neonatal period.

The male predominance observed in this study is in line with the findings of most authors [2,3,5,8,11,13]. However, the explanation for this gender difference is not yet wellknown.

In this study, newborns suffering from RD were more frequently delivered vaginally rather than by cesarean section. Although this finding is similar to some authors [10-12,14,15], it contradicts the observations of other authors who indicate a greater frequency of RD in cesarean birth [3,5,8,13]. It may be due to the passage of the newborn through the birth canal that compresses the thorax, facilitating the expulsion of lung fluid, and promoting airway drainage during vaginal delivery. On the other hand, the newborn is extracted directly from the uterus without passing through the vaginal canal in a cesarean section and this procedure does not allow adequate evacuation of lung fluid, which can contribute to the reduced frequency of RD in the newborn. However, it is important to note that the occurrence of NRD depends on many other factors, such as prematurity, infections, malformations, meconium aspiration syndrome, etc. The mode of delivery is therefore only one of many factors that can influence the respiratory status of the newborn.

In this study, RD was more prevalent among term newborns, which is consistent with the findings reported by most authors [2,3,8-12,15]. However, other authors have reported a predominance of RD in preterm newborns [6,14,16], which contradicts our results. This difference may be explained by the varying proportion of term and preterm newborns in the different study samples. NRD obeys different mechanisms. The most common cause of NRD among term newborns delivered by cesarean section, especially before the commencement of labor, is the inability to expel lung fluid. On the other hand, NRD is mainly caused by hyaline

membrane disease in premature newborns, the frequency of which decreases with gestational age. The frequency is 60% in premature newborns under 28 weeks, 30% between the 28$^{th}$ and 34$^{th}$ weeks, and less than 5% in children born at 35 weeks or more [17].

This study revealed that NRD was more common in newborns with normal birth weight which corroborates the findings of some authors [5,10-12]. However, on the other hand, it contradicts the observations of other authors [2,13,14,16] who report a greater frequency of NRD in LBW newborns. The explanation for this difference could be similar to that concerning birth term. In practice, term and birth weight overlap. Normal-weight newborns are generally born at term, while the majority of LBW are born prematurely. Ultimately, it is the level of lung maturity that would distinguish these groups of newborns.

In this study, 15.9% of newborns suffering from RD had an Apgar score of less than 7 at the 5$^{th}$ min of life which is lower than that reported under our conditions by Osara*et al* [9] where 64.7% of newborns had lower Apgar scores. An Apgar score of less than 7 defines perinatal asphyxia and the difference in the Apgar scores among various studies is probably due to the incidence of perinatal asphyxia in the study populations.

Fever was frequent at 32.1% of newborns, which was presumptive of the infectious origin of NRD.

Cyanosis was found at a frequency of 74.1% in this study which is much higher than that reported by other authors, including Kuti *et al* [11] (5.6%), Bajad*et al* [18](26.7%), Ali *et al* [13] (42.5%), and Osara*et al* [9] (64.7%). The difference could be explained by the importance of hypoxia, which was reported by $SpO_2$ in more than half of the newborns in the present study. The other signs of RD are found with varying frequency by other authors (Table 6).

***Table 6: Frequency (%) of signs of neonatal respiratory distress, compared in different studies***

| **Sign of neonatal respiratory distress** | **This study** | **Osara*et al*** **[9]** | **Bajad*et al*** **[18]** | **Sbzehei et al [19]** | **Barkiya *et al*** **[20]** |
|---|---|---|---|---|---|
| Cyanosis | 74,1 | 64,7 | 26,7 | 45,2 | 41 |
| Polypnea | 45,2 | 45,6 | 98,3 | -[a] | 61 |
| Bradypnea | 25,4 | 5 | -[a] | -[a] | -[a] |
| Grunting | 65,6 | 45,6 | 26,4 | 61,3 | 41 |
| Nasal flaring | 92,1 | 68,2 | -[a] | 16,1 | 80 |
| Intercostal retraction | 70,5 | 82,7 | 76,3 | 75,3 | 81 |
| Xiphoid retraction | 60,7 | 47,1 | -[a] | -[a] | -[a] |
| Supra-sternal retraction | 57,4 | -[a] | -[a] | -[a] | -[a] |
| Thoracic-abdominal rocking | 33,1 | 53,3 | -[a] | -[a] | -[a] |

[a]*Unreported*

The difference in frequency between authors is probably due to the difference in severity of NRD.

In this study, RD was of moderate severity in the majority of cases according to the Silverman and Andersen score. As shown in Table 7, this result is similar to that reported by many authors,

but different from the result reported in Nigeria [11], in whom the frequency of distress decreases with the Silverman and Andersen score.

***Table 7: Comparative frequency of severity of neonatal respiratory distress in Burkina Faso, Nigeria, and India.***

| **[Author] (Country)** | **Severity of neonatal respiratory distress according to Silverman and Andersen score (%)** | | |
|---|---|---|---|
| | **Mild** | **Moderate** | **Severe** |
| This study (Burkina Faso) | 20,3 | 68,5 | 11,1 |
| Osara*et al* [9](Burkina Faso) | 33,3 | 37,5 | 29,1 |
| Kuti *et al* [11] (Nigeria) | 61,6 | 32,8 | 5,6 |
| Bajad*et al* [18] (India) | 4,5 | 63,1 | 33,3 |

Barring unreported cases, the causes of NRD are well documented and classified [21,22]. Respiratory pathologies are the main causes of NRD, according to most authors [6,7,19,20], although their frequency may vary, respiratory causes are followed by perinatal asphyxia, sepsis, and congenital malformations.

What is remarkable in this study is the predominance of sepsis, whether in the form of septicemia or local respiratory infection, as well as, perinatal asphyxia as the two main causes of NRD in our setting, corroborating the findings reported by another local author [9]. This also confirms the prevalence of these two conditions in neonatal morbidity in Burkina Faso [23,24]. In developing countries, the incidence of these two public health problems can be reduced by taking several actions such as regular monitoring of pregnant women to detect and treat maternal infections, delivery in health centers by qualified personnel, and rigorous application of essential newborn care.

The unreported finding is poisoning from traditional products, which accounts for 2.7% of NRD cases in this study. Practices harmful to the health of newborns, such as purging and force-feeding, are still widespread in our communities. These practices generally use products based on traditional medicinal plants which often create a pseudo-occlusion that leads to abdominal distension, sometimes so great that it compresses the newborn's thorax, leading to RD.

In terms of diagnostic resources and investigations, blood gases can provide clues to the etiology of RD but unfortunately, this test is not available in our working environment. In this study, radiography, an essential investigation, was performed in only half the cases. Due to material constraints, it is not possible to perform X-rays at the patient's bed, which limits its use.

Treatment of NRD should be both generalized and disease-specific, and follow updated neonatal resuscitation protocols [25,26]. The treatments administered in this study are in line with local guidelines [27]. However, limitations lie in the absence of CPAP, intubation, and exogenous surfactant. Etiological treatment was limited to the antibiotics available to treat infections. Surgical conditions were not always accessible, while heart disease was generally evacuated to developed countries, mainly to France. The therapeutic strategy was similar to that of other local authors, given the context [9]. Improving the technical equipment of NU will enable us to improve the treatment of NRD in developing countries.

The mortality rate of 27.2% observed in this study is higher than that reported by some authors, which ranges from 2% to 24.5% [7,8,10-12,14,18-20].
Several factors, such as prematurity, LBW, severity of RD, and quality of care, could influence the death of newborns [9,18], which could explain the difference in mortality rates

between authors. In addition to these factors, it is likely that other elements, such as the underlying cause of NRD, diagnostic and therapeutic methods used, also play a role in the variation in mortality of NRD between authors. The establishment of a prognostic score would be extremely useful in improving the management of these newborns in RD.

This study identified the two main causes of NRD, namely sepsis and perinatal asphyxia, which are also the main causes of death. This result is similar to that reported by other authors in Burkina Faso [9]. As the geographical and working conditions are similar, the results of the studies are similar. However, with the exception of perinatal asphyxia [3,7,8,10,14,18], other authors more frequently report hyaline membranes disease [3,7,8,10,14,18], malformations [3,10,18], and meconium aspiration syndrome [7,14,18] as the main causes of death in newborns.

**Recommendations**

To combat causes of death such as sepsis, perinatal asphyxia, hyaline membrane disease, malformations, and inhalation of meconium fluid in newborns, the following recommendations should be adapted: a) Improving rigorous hygiene practices in healthcare facilities, including hand washing, sterilization of equipment and surfaces, and proper management of medical waste in order to reduce sepsis cases. b) Strengthening obstetric care in order to reduce the risk of perinatal asphyxia by training medical staff in safe birthing techniques, closely monitoring the well-being of the fetus during labor, and taking emergency measures in the event of complications, c) Promoting awareness and education among pregnant women, their families and communities regarding the risks associated with prematurity and hyaline membrane disease, malformations, and inhalation of meconium fluid. Education campaigns should emphasize danger signs, prevention practices, and the importance of regular medical follow-up

during pregnancy, d) Strengthening screening and diagnostic services to detect congenital malformations and respiratory problems in newborns. This would enable rapid and appropriate intervention to minimize risks, e) Improve access to healthcare by ensuring equitable access to maternal and child healthcare by providing adequate infrastructure, sufficient medical resources, emergency transport services, and universal health coverage programs, f) Encourage research and innovation in the field of maternal and child health to develop new strategies for the prevention, screening, and treatment of respiratory problems and malformations in newborns.

**Study limitations**

This retrospective study came up with a number of constraints that may attenuate the significance of the results. The absence of information on certain variables led to high non-response rates, and the mono centric nature of the study may have generated selection bias. The unavailability of tests such as blood gases may not have enabled the full severity of RD to be assessed; the absence of CPAP and surfactant did not allow optimal treatment of newborns, which undoubtedly influenced the mortality observed.

**Conclusion**

This study showed that RD is a frequent reason for the hospitalization of newborns in our neonatology unit. It is a diagnostic and therapeutic emergency whose main causes are sepsis and perinatal asphyxia. The lethality of NRD remains high in our context of a country with limited resources. To improve the management of NRD and achieve sustainable development goals, it is essential to implement a national strategy to combat neonatal infections and perinatal asphyxia and to equip or reinforce neonatology units with the necessary diagnostic and therapeutic resources.

## List of abbreviations

CHUP-CDG: Centre hospitalieruniversitairepédiatrique Charles de Gaulle

CPAP: Continuous positive airway pressure

NRD: Neonatal respiratory distress

LBW: Low birth-weight

NU: Neonatal Unit

RD: Respiratory distress

SpO2: Peripheral pulsed oxygen saturation

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## Ethical approval and consent

We obtained an institutional approval letter from Centre hospitalieruniversitaire Charles de Gaulle prior to the commencement of the study with approval number 2022-1540/MSHP/SG/CHUP-CDG/DRH/SRF, July 22, 2022. The necessity to obtain written consent was waived because of the retrospective nature of this study. In addition, the data recorded was anonymized. Above all, this study was entirely conducted ain accordance with the 1964 Declaration of Helsinki ethical principles for medical research on human subjects.

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